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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,744	02/02/2004	Christopher Hunter	120-000220US	4909
22798 7590 10/14/2009 QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			EXAMINER WOODWARD, CHERIE MICHELLE	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 10/14/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/768,744	Applicant(s) HUNTER ET AL.	
	Examiner Cherie M. Woodward	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,11-13,18-21,24-26 and 73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,11-13,18-21,24-26 and 73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/20/2009 & 9/21/2009</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1647

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/20/2009 has been entered.

Formal Matters

2. Claims 2-5, 7-10, 14-17, 22-23, and 27-72 have been cancelled by Applicant. Claims 1, 6, 11-13, 18-21, 24-26, and 73 are pending and under examination.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on 7/20/2009 and 9/21/2009 have been considered by the examiner. Annotations have been made noting that two of the references are abstracts only. Signed copies are attached hereto.

Response to Arguments/Amendments

Claim Objections

4. The objection to claims 21 and 73 is withdrawn in light of Applicant's amendments.

Claim of Benefit and Rejections Maintained

Priority/Benefit

5. Applicant repeats arguments that have been raised multiple times, directed toward the claim of benefit. The examiner has responded multiple times that Applicant's claim for benefit to provisional application 60/44,494, filed 31 January 2003, and provisional application 60/519,074, filed 10 November 2003, is proper, but benefit is not accorded to the provisional filings for the reasons set forth in detail of record. Benefit remains accorded to the instant filing date of 2 February 2004.

Art Unit: 1647

Provisional Obviousness-Type Double Patenting Rejection

6. The provisional rejection of claims 1, 6, 11-13, 18-23, and 73 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-24 and 26-28 of copending Application No. 11/880,121, is maintained for the reasons of record.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 6, 11-13, 18-21, 24-26, and 73 remain rejected under 35 U.S.C. 102(a) and 35 USC 102(e) as being anticipated by Timans *et al.*, US Patent Application Publication 2002/0164609 A1 (publication date 7 November 2002) now US Patent 7,148,330 (12 December 2006, filed 30 November 2001), for the reasons of record and the reasons set forth herein.

Applicant responds to all of the rejections under 35 USC 102(a), (b), and (c) (referring to the Timans *et al.*, publication, the DeSavage *et al.*, publication, the Bennett *et al.*, publication, and the Matthews *et al.*, patent in one responsive argument. As such, Applicant's arguments will be presented under the instant rejection over the Timans *et al.*, reference and the arguments will not be repeated in response to the other individual rejections, below.

Applicant argues that "the office has yet to point out where the prior art teaches the steps of administering an IL27-R agonist to a person selected to be in need of immune suppression" (Remarks, p. 8). As previously stated of record on several occasions, Timans *et al.*, teach the administration of an **agonist** of IL-D80 [p28], IL-27, or WSX-1/TCCR, "in the treatment of abnormal medical conditions, including immune disorders, e.g...inflammation..." (p. 4, col 1, paragraph 0039) [emphasis added].. The agonists taught by Timans *et al.*, include receptor [WSX/TCCR] agonists (p. 4, col 1, paragraph 0039), and agonists where the binding component comprises a Fv, Fab, or Fab2 fragment (p. 2, col 2, paragraph

Art Unit: 1647

0019). Additionally, Timans *et al.*, teach the therapeutic use of stimulatory antibodies as agonists (p. 12, col 2, paragraph 0135). Further, Timans *et al.*, teach the role of the receptor subunit WSX-1/TCCR in inflammatory responses (p. 15, col 2, paragraph 0161).

The examiner has not ignored the cited art. To the contrary, the examiner has specifically pointed out where in the prior art the teachings of Applicant's claims may be found (see Remarks, pp. 8-9).

Regarding Applicant's arguments that the extrinsic evidence post-dates Applicants' filing date and priority date (Remarks, pp. 10-11). Applicant is reminded that Applicant has only been accorded the benefit of the filing date of the instant application, that of 2 February 2004, for the reasons set forth of record. Accordingly, any extrinsic evidenced used by the examiner in response to Applicant's argument is sufficient to show the state of the art prior to or at the time the instant application was filed.

Applicant's arguments have been responded to in detail in the responses of record. Applicant restates and incorporates arguments that have previously been made and responded to (Remarks, p. 11). The instant claims remain anticipated.

9. Claims 1, 6, 11-13, 18-21, 24-26, and 73 remain rejected under 35 U.S.C. 102(b) as being anticipated by DeSavage et al., WO 01/29070 (26 April 2001) (see also US Patent Application Publication 2004/0234522 A1) for the reasons of record and for the reasons set forth below.

Applicant responds to all of the rejections under 35 USC 102(a), (b), and (c) (referring to the Timans et al., publication, the DeSavage et al., publication, the Bennett et al., publication, and the Matthews et al., patent in one responsive argument.

Applicant's arguments with respect to DeSavage et al., have been fully considered, but they are not persuasive. Applicant is directed to the examiner's response, set forth above. Additionally, as stated of record, DeSavage specifically teaches methods of treatment of diseases characterized by immune hyperactivation (see pages 59-63) using TCCR (WSX-1) polypeptides and antibodies, including agonist antibodies. Additionally, DeSavage also specifically contemplates inhibition of molecules with proinflammatory properties (i.e. immune suppression) at p. 63, line 36. The instant claims remain anticipated.

10. Claims 1, 6, 11-13, 18-21, 24-26, and 73 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al., WO 97/25425 (17 July 1997), for the reasons of record and for the reasons set forth herein.

Art Unit: 1647

Applicant responds to all of the rejections under 35 USC 102(a), (b), and (e) (referring to the Timans et al., publication, the DeSavage et al., publication, the Bennett et al., publication, and the Matthews et al., patent in one responsive argument.

Applicant's arguments with respect to Bennett et al., have been fully considered, but they are not persuasive. Bennett et al., teach methods of using the WSX-1 ligands (abstract), WSX-1 fusion proteins (p. 4) and anti-WSX-1 receptor agonist antibodies (pp. 4-5) for the treatment of hematopoietic disorders such as leukemia, lymphoma, and anemia and for enhancement of lymphopoiesis in disorders such as HIV/AIDS and infections (p. 6). Additional therapeutic uses for the WSX-1 receptor are taught on p. 41. Therapeutic uses for WSX-1 receptor ligands and antibodies are taught on pp. 56-59. The instant claims remain anticipated.

11. Claims 1, 6, 11-13, 18-21, 24-26, and 73 remain rejected under 35 U.S.C. 102(e) as being anticipated by Matthews *et al.*, US Patent 7,074,397 B1 (11 July 2006, benefit to 8 January 1996), for the reasons of record and the reasons set forth herein.

Applicant responds to all of the rejections under 35 USC 102(a), (b), and (e) (referring to the Timans et al., publication, the DeSavage et al., publication, the Bennett et al., publication, and the Matthews et al., patent in one responsive argument.

Applicant's arguments with respect to Matthews et al., have been fully considered, but they are not persuasive. Matthews et al., teach methods of using agonist antibodies that bind to the WSX receptor (IL-27R) (column 3, lines 38-40, 46-47; column 14, lines 61-64, column 17, lines 14-16, column 44, line 22; column 80, lines 47-48 and 58-59; and column 45, beginning at line 36 to column 50) in the treatment of hematopoietic disorders, infections, and malignancies (column 50, lines 58-67 to column 51, lines 1-13). Applicant's definition of the patient population includes individuals with the same disorders taught by the '397 patent as being treatable with agonist antibodies that bind the WSX receptor (IL-27R) (see especially, column 50, lines 58-67 to column 51, lines 1-13) (compare claims 21 and 73, especially the listed disorders of: tumor metastasis, leukemia, multiple myeloma, myelogenous leukemia, septic shock, fever, Reiter's syndrome, enteropathic arthritis, Lyme disease, staphylococcal-induced arthritis, rheumatic fever, pemphigus, and an inflammatory condition resulting from infection). The instant claims remain anticipated.

Conclusion

NO CLAIM IS ALLOWED.

Art Unit: 1647

THIS IS A FIRST ACTION FINAL.

12. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647